

REMARKS

I. Status of the Application and Claims

Claims 17-98 are pending in the application and under examination. All of the pending claims stand rejected.

Without intending to change the scope of the claims. Applicants have amended claims 17-52 and 78. Support for the amendments is found, for example, at page 11, lines 1-3, and in the Abstract. The amendments do not add new matter to the application.

II. Summary of Interviews on May 27 and June 1

Applicants thank Examiner Weber for taking the time to discuss this application with Applicants' representative on May 27 and June 1. In those interviews, Examiner Weber and the undersigned discussed the rejections set forth in the Office Action mailed February 11, 2009. In particular, the rejections were discussed in the context of the prosecution to date in the application and the arguments for patentability advanced by Applicants in response to earlier Office Actions. In the interview on June 1, Examiner Weber advised the undersigned of the status of the pending rejections and the participants discussed amendments and arguments that should put the application in condition for allowance. Applicants believe this response fully presents such amendments and arguments. If the Office believes that all of the issues raised in the examiner interviews have not been addressed, Applicants respectfully request that the Office call their undersigned representative to discuss what more is needed to place the application in condition for allowance.

III. Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 17-98 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for the reasons set forth in the Office action at pages 2-7. The Office has agreed to withdraw the rejections. See Communication mailed June 3, 2009, continuation sheet. Accordingly, Applicants provide no response to these rejections.

IV. Rejections Under 35 U.S.C. § 112, First Paragraph

A. Claims 17-51 Are Supported by the Specification

The Office rejects claims 17-51 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Office action, p. 2. The Office contends that the language “an antibiotic added to the medium before the medium gels” is new matter that is not supported by the specification. *Id.* Applicants traverse.

For the sake of a clear record, Applicants note that the claim language at issue was entered into the claims with the Amendment filed on January 10, 2008. The Office rejected the language as new matter in the Office Action mailed February 21, 2008. Applicants argued that the language was supported by the specification in their response filed March 18, 2008, pp. 3-4. The Office accepted that the language found support in the specification in the Office Action mailed June 13, 2008, p. 3.

In view of the record, Applicants submit that the language is fully supported by the specification. Solely to advance prosecution, however, and without changing the scope of the pending claims, Applicants have amended claims 17 and 37 to replace the phrase “before the medium gels” with the equivalent phrase “before the medium is solid.” As the Office acknowledges on the continuation sheet of the Communication

mailed June 3, 2009, the phrase “before the medium is solid” is fully supported by the specification, for example, on page 11, lines 1-2.

For at least these reasons, Applicants respectfully submit that the claims do not recite new matter and, therefore, they request that the Office withdraw this rejection.

B. Claims 17-98 Are Fully Enabled

Claims 17-98 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabled by the specification. Office Action, pp. 9-10. Specifically, the Office contends: (1) the specification “does not teach the various product by process to prepare the claimed ‘gelled culture medium’” recited in claims 17 and 51; (2) claims 17, 37, 51, and 78 “lack the specific agent or component for the culture medium”; and (3) “[t]he claims are broader than the enabling disclosure with respect to the components in i) ‘medium’, ii) ‘nutrients’ and iii) the method for detecting the inoculated medium” *Id.* at p. 10. Applicants traverse the rejection.

The Office has the initial burden of establishing a reasonable basis to question the presumptively enabling teaching of the specification, and to properly sustain a rejection for lack of enablement must provide a rational explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure. See M.P.E.P. § 2164.04, 8th Ed., July 2008 Rev. (citing *In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993)). Applicants respectfully submit the Office has not carried its burden of showing a *prima facie* lack of enablement for the claims because the Office has not identified any “specific findings of fact, supported by the evidence” to explain why the currently pending claims are not enabled. *Id.*

Nevertheless, Applicants respectfully submit that the claims are fully enabled by the specification. For instance, pages 4-9 and Examples 1 and 2 of the specification

provide exemplary methods and formulations for practicing the claimed invention.

Moreover, as the Office acknowledges, methods and formulations for making and detecting inoculated culture medium were known in the art, as evidenced, for example, by U.S. Patent No. 6,696,239, which is cited on page 10 of the Office Action.

For at least these reasons, Applicants respectfully request that the Office withdraw this rejection.

V. Rejections Under 35 U.S.C. § 103

Claims 17-98 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over the following combinations of references:

- Merlino *et al.*, New Chromogenic Identification and Detection of *Staphylococcus aureus* and Methicillin-Resistant *S. aureus*,” J. Clin. Microbiol., 38:2378-80 (June 2000) (“Merlino”) in view of Felten *et al.*, “Evaluation of Three Techniques for Detection of Low-Level Methicillin-Resistant *Staphylococcus aureus* (MRSA): a Disk Diffusion Method with Cefoxitin and Moxalactam, the Vitek 2 System, and the MRSA-Screen Latex Agglutination Test,” J. Clin. Microbiol., 40:2766-71 (August 2002) (“Felten”);
- Merlino and Felten in view of U.S. Patent No. 5,883,074 to Boggs *et al.* (“Boggs”);
- Merlino and Felten in view of U.S. Patent No. 6,221,859 to Dorso *et al.* (“Dorso”);
- Merlino and Felten in view of U.S. Patent No. 6,294,527 to Hanaki *et al.* (“Hanaki”);
- Merlino and Felten in view of U.S. Patent No. 6,548,268 to Rambach (“Rambach”);
- Merlino and Felten in view of Carricajo *et al.*, Comparative Evaluation of Five Chromogenic Media for Detection, Enumeration, and Identification of Urinary Tract Pathogens, Eur. J. Microbiol. Infect. Dis., 18:796-803 (1999) (“Carricajo”), and in view of L. Pead *et al.*, Staphylococci as Urinary Pathogens,” J. Clin. Pathol., 30:427-31 (1977) (“Pead”);

- All of the above combinations of references further in view of U.S. 6,696,239 to Bochner ("Bochner 1"), U.S. Patent No. 5,989,853 to Bochner et al. ("Bochner 2"), and U.S. Patent No. 6,130,057 to Gosnell et al. ("Gosnell").

Office Action. pp. 12-20. Applicants traverse these rejections.

All of the rejections made by the Office in the February 11, 2009, Office Action rely on the combination of Merlino and Felten. The Office cites Merlino for allegedly disclosing "the color reagent and staphylococcus aureus growth ingredients in the gel [of claims 17-98]," and cites Felten for allegedly disclosing "using the antibiotic [of claims 17-98] to distinguish resistant from non-resistant staphylococcus aureus." Communication mailed June 3, 2009, continuation sheet. The Office then contends that it would have been obvious to add a second or third generation cephalosporin to the CHROMagar medium used by Merlino to distinguish between methicillin-resistant and methicillin-susceptible strains of *S. aureus* based on the teachings of Felten. Office Action mailed February 11, 2009, pp. 14-15.

Applicants traverse the rejections set forth in the February 11, 2009, Office Action, for the reasons of record as set forth in the Responses dated January 10, 2008, and October 28, 2008, further supplemented as follows, and in view of the communication mailed June 3, 2009, (continuation sheet).

Applicants have previously explained why one of ordinary skill in the art would have had no reason to combine the teachings of Felten with those of Merlino with a reasonable expectation of success (*e.g., inter alia*, because the disk-diffusion technique disclosed in Felten is not analogous to the technique disclosed by Merlino in which the antibiotic is incorporated into the medium). In the communication mailed June 3, 2009, (continuation sheet), the Office recognizes that the claimed invention "has disclosed

advantages of higher sensitivity and speed” compared to the combined teaching of Merlino and Felten, pointing to Example 2 in support of that conclusion. Thus, Applicants maintain their position that the claims are not rendered obvious by Merlino in view of Felten. *See, e.g., KSR Int’l. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007) (discussing that when a patent application claims a combination of prior art elements that work together in an unexpected and fruitful manner, the invention is non-obvious). Moreover, none of the secondary references cited by the Office cure the deficiencies in the combined teachings of Merlino and Felten.

For at least these reasons, Applicants respectfully request that the Office withdraw the obviousness rejection over the combination of Merlino and Felten, as well as the rejections based on Merlino and Felten in combination with the different secondary references.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration of this application and timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: June 9, 2009

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